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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow Classen

Application No.: 10/081,705 **Art Unit: 1273**

Filing Date: 02/21/2002 **Examiner: Etienne LeRoux**

Title: Computer Algorithms and Methods for Product Safety

DECLARATION OF JOHN BARTHELOW CLASSEN UNDER 37 C.F.R. §1.1.32

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

I, JOHN B. CLASSEN, do declare and state that:

1. I am a physician scientist and the inventor of the patent application under review as well as U.S. Patent Nos. 6,219,674 and 6,584,472. I am also President and CEO of Classen Immunotherapies Inc. In addition, I am the inventor on a number of other patents relating to vaccine safety, including U.S. Patent Nos. 5,723,283; 5,728,385; 6,420,139; 6,638,739; and 7,008,790. My curriculum vita is available to the Examiner upon request. On several occasions I have provided expert testimony on vaccine safety to the Congress of the United States.

2. I have extensively researched the performance of scientists and events in the pharmaceutical industry, and the industry itself, and to the best of my knowledge before my invention, those in the industry believed that generic drug competition was inevitable once patents expired claiming a composition of matter, a first therapeutic use of the composition, and/or a method of its manufacture, and that there was no legal way of stopping generic competition, except through specific legislation from Congress.

Furthermore, it was the accepted wisdom of the industry that there was no positive value to be gained from discovering adverse events or warning consumers about such adverse events. Prior to my invention, those in the industry had demonstrated no way to commercialize or profit from warning people about any risk(s) associated with using a product.

3. My invention revolutionized the pharmaceutical industry in that now, those, who have learned of my teachings, know that it is possible to completely inhibit generic drug competition by continually finding new adverse events resulting from the use of a product, and patenting the disclosure of these adverse events. I have been asked to give presentations, including these findings at three meetings held by the Center for Business Intelligence, and I have also given presentations to many pharmaceutical companies, including GlaxoSmithKline, Johnson and Johnson, AstraZeneca, Aventis, Taro, Supernus, MedPointe, Cypress Bioscience and others. It is my belief that my technology is being used, without my permission, at least by Elan Pharmaceuticals, Inc., King Pharmaceuticals, Inc., and Mutual Pharmaceutical Company. See, Civil Action No.: 1-04-CV-03521 WDQ), *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc., et al.* My invention has been the subject of interest to the lay press (**Exhibit A**) and discussed by the U.S. Senate (**Exhibit B**).

4. I believe that my interaction with Elan Pharmaceuticals, is evidence of non-obviousness of my invention, demonstrating unexpectedness and superiority of outcome over the prior art, evidence of commercial success, and evidence of copying. In particular, Elan's use of the technology shows that they could have prevented generic competition, but did not believe it was possible until after hearing my presentation in 2001. If, prior to 1999, Elan had known that it was possible to prevent generic drug competition to their existing products (Skelaxin and Zanaflex) for their existing indications (muscle relaxants), then Elan would not have waited so long (until November 2001) before seeking new patents. Had they not delayed, Elan would not have lost their lead product, Zanaflex, to generic drug competitors. There was a wealth of safety data available that Elan could have found, inexpensively and quickly, but they did not know what information to look for and how to commercialize that data.

5. I spoke with two Elan employees, Nancy Santilli and Cara Pellegrini, when the attended my presentation at the Center for Business Intelligence meeting, November 15-16, 2001. (**Exhibit C**). Both were involved with Elan's muscle relaxant business, which included Skelaxin and Zanaflex. Neither drug was protected by a patent, and each drug faced imminent competition from generic drug manufacturing companies. Ms. Pellegrini was at the time assigned to obtain business intelligence for Elan and to bring new technologies to the company. After hearing my talk and receiving copies of my patents, these individuals returned to Elan and talked with the company's patent attorney.

6. Within weeks of meeting with me, Cara Pellegrini filed a patent application claiming a drug/food interaction on Zanaflex (now U.S. Patent No. 6,455,557, filed November 28, 2001), and her co-worker filed a patent application claiming a drug/food interaction on metaxalone (now U.S. Patent Nos. 6,407,128 and 6,683,102, filed December 3, 2001). The '102 patent is, in fact, the subject of my patent infringement suit with Elan. The Elan patents cover an adverse event, i.e., a drug/food interaction (drug interaction), that is specifically covered by my '674 patent (claims 28, 57, 82). While Elan relied heavily on the income from these two muscle relaxants (approximately $400 million dollars for the year 2005), generic drug competition was an imminent threat. Nevertheless, Elan failed to file patent protection for the drug/food interaction until weeks after hearing me present the method claimed in my patent. In fact, Elan already had the data on the drug/food interactions in their database, but they did not screen the database to uncover the patentable information until after learning of the technique for doing so from my presentation of my invention.

7. Within weeks of filing the subject patent applications for Zanaflex and Skelaxin, I was contacted by Steve Cartt, the director of Elan's muscle relaxant division. He said that both Nancy Santilli and Cara Pellegrini reported to him, and that Elan was interested in licensing the technology in the '674 and '472 patents. On January 4, 2002 Cartt told me that he believed my technology would be of great value to Elan and that they wanted my help for using my technology to generate more patents for Elan. Cartt then arranged a conference call on January 11, 2002 with Elan's chief patent attorney, Jean Duvall, during which we discussed my patents. After the conference call, I was told

that Elan wanted to continue to work with me to strengthen their patent portfolio, and they asked me to submit an document to begin exploring possible licensing arrangements. Elan continued to ask me to provide help to them for strengthening their patent portfolio. A series of e-mails ensued (**Exhibit D**).

8. Before Elan was issued patents on either of the drug/food interactions, a generic drug competitor of Zanaflex entered the market, Elan's sales dwindled and Elan lost interest in the product. However, Elan's patent on informing patients about a drug/food effect with Skelaxin was issued before the generic drug competitors entered the market. Elan and its partner King Pharmaceutical changed the labeling to include information on drug-food interactions and have kept generic drug competitors off the market by arguing that competitors must disclose the patented safety information. However competitors are blocked from disclosing the necessary safety information because of the patents. To date, there is no generic drug competitor in the market, despite the fact that the FDA approved a generic product, and generic drug manufacturers have tried to enter the market. The product sells about $400 million a year, or about $100 million a quarter (**Exhibit E**). More recently, generic drug competitors have begun copying my technique in the hope of forcing Elan and King to cross-license the patents based on claims relating to the discovered drug/food interaction. Mutual Pharmaceutical Company, a generic manufacturer, has received its own patent (US Patent No. 7,122,566, **Exhibit F**) resulting from an identified drug/food interaction.

9. During my many interactions with Elan, often initiated by Elan, they never said, suggested or implied that they believed my patents were anything but valid, and they never indicated that my inventions were not novel. In fact, Steve Cartt, who worked closely with the chief patent attorney, Jean Duvall, praised me for my help and the originality and usefulness of my technology. Regardless of what they may now say in this proceeding, I believe Elan's actions demonstrate that my invention is novel and that the methods were non-obvious. If the patent decision-makers at Elan had thought my patents were obvious as they now suggest in their Request for Reexamination, why would they continue to hold discussions with me for 6 months and continually ask me for help? In fact, Elan's own actions by its officers and employees are proof that, at the filing date, my technology was not obvious to those skilled in the art.

10. Elan's behavior cannot be ignored, and the secondary considerations demonstrated by Elan in 2001 and 2002 with regard to my technology, demonstrate that others in the art also believed it to be non-obvious. Moreover, it shows that my invention offered unexpected results in the art, along with a method for blocking competition from generic drug manufacturers. It also shows that one can create tremendous value from warning consumers about adverse risks of using a product. Neither my method for blocking competition or for creating value from a finding of an adverse event had been accomplished or proposed in the art prior to my invention. In addition, the 2001 and 2002 response by Elan upon learning of my invention, demonstrates by all 5 recognized, secondary consideration criteria for establishing non-obviousness of an invention in view of the prior art. This evidence relates to the real world activities of others, and indicates what one of ordinary skill in the art would or would not have done.

(a) *Commercial success of the claimed invention*: From my invention Elan learned to scan their databases to detect patentable information that will permit them to keep competitive generic drugs off the market. Elan did not file patents on this information until after they had met with me. Despite the fact that they had the data available in their databases, and they knew that something had to be done to prevent generic drug competition, they did not know how to find the valuable data until they met with me. However, once Elan was taught my invention, they learned how to quickly and efficiently search and find valuable data to prevent generic drug competition.

(b) *Long felt need in the art for a solution to a recognized problem*: It was, and continues to be, well-known in the art, that generic drug competition will develop as soon as the original composition of matter, first therapeutic use, and sometimes, method of manufacturing patents expire for a successful and profitable drug. Consequently, companies have looked for all sorts of ways to inhibit generic competition. Moreover, there was a need to stimulate companies to look for and disclose risks associated with their products.

(c) *Failure of others to solve a known problem*: There have been numerous attempts by others to block generic drug competition, but they have failed to prevent generic drug competition of the first therapeutic use. Also,

finding adverse events has made headlines in recent years, and there is a consensus in the art that such adverse events should have been detected as soon as possible. Yet, there was little incentive for manufacturers to invest heavily in finding out about the risks associated with the use of their products. Conversely, there is a significant incentive for finding new drug indications.

(d) *Skepticism of experts*: It was believed at the filing date of my '674 patent that it was not possible to completely prevent generic drug competition for the original formulation and original indication of a compound after the original patents had expired.

(e) *Copying of the invention in preference to the prior art*: In the actions described above, it is clear to me that Mutual Pharmaceuticals Co. copied my invention and obtained their own patent on a drug-drug indication involving a pre-existing compound.

11. In summary, I believe that, at least, the above-described actions by Elan and by Mutual Pharmaceuticals prove that my inventions were not obvious.

12. I declare that adverse events are not equivalent to outcome studies or their results. Outcome studies most often relate to efficacy.

I hereby declare further that all statements made herein of my own knowledge are true and that all statements on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the captioned patent.

Date: March 29, 2007

John Barthelow Classen

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When a company claims that its new patented system is expected to have 'a major impact' on the pharmaceutical and chemical industries, one is inclined to sit up and pay attention. Baltimore based Classen Immunotherapies has just been issued US patent number 6,219,674 for a 'business method' which leads to the inhibition of generic products by patenting the disclosure of new adverse event information.

The key to the Classen claim is that a manufacturer of a product, which continues to discover new adverse events associated with that product can 'patent the disclosure of this new adverse event information and thereby prevent generic competition indefinitely'.

Classen continues: 'Even in situations where a regulatory agency such as the FDA is unwilling to force a generic product with inadequate warnings off the market, courts of law have stepped in and taken harsh actions against companies for failing to warn about adverse events. Manufacturers who continue to perform inadequate safety testing of their products could lose exclusivity of their products long before the original patent on their product expires.'

After a struggle to understand this patent, we spoke to Bart Classen and he explained it thus: "Yes, it is a business method, which amongst other things, screens for new adverse events in drug interactions. If, for example, a drug is about to go off patent, you can find a new use for it, for example in a way which makes it safer, and take out a patent." This prevents imitators from manufacturing competitive generic versions.

If a generic competitor licenses the new business method patent from Classen, or discovers and patents a new adverse event associated with a brand name product, this generic competitor can then force the original manufacturer to remove the product from the market or demand from the manufacturer a license to manufacture the product.

So we asked Bart Classen if he was selling generic competitors a device for competing with leading manufacturers. Or threatening to sell such a device if the principles did not buy it first?

He replied: "We are offering two things: to help manufacturers

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maintain their monopoly, and to protect them from pirates. They can always say 'Screw the pirates — we'll get them in court!'"

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Press Release

FOR IMMEDIATE RELEASE: April 23, 2002

SCHUMER: DRUG COMPANIES STOOPING TO NEW LOW BY SEEKING PATENTS ON SAFETY INFO

Senator says patent abuses are costing consumers, businesses, and insurers millions

Schumer presses GAAP legislation that would reform Hatch-Waxman to ensure that low-cost drugs inject a needed dose of competition into the drug industry

US Senator Charles E. Schumer, co-author of the Greater Access to Pharmaceuticals (or GAAP) Act, offered testified at the Senate Commerce Committee Hearing on Generic Pharmaceuticals: Marketplace Access and Consumer Issues. Schumer spoke about a new tactic that the name-brand pharmaceutical companies are using to block the entry of low-cost, generic drugs that involves seeking patents on information related to safety. The FDA has long determined that safety information is part of the public domain.

Schumer pointed to the example of the pain medication, Ultram. Although five generic versions of it were about to be approved in January of this year, its producer, Ortho McNeill, filed a patent on a slightly altered dosing schedule, a schedule which is obvious to most pharmacists, but one which they claim is essential to the safety of the drug. Under Hatch-Waxman, patenting this information would at the very least automatically keep the generic off the market for 30 months. If the patent is upheld in the courts, it would prevent competition until 2019. With sales of over $690 million per year, these delays will cost consumers over $3 million per week. Schumer made the following statement at the hearing:

"I would first like to thank Chairman Hollings for scheduling a hearing on such an important issue, as well as Senator Dorgan and Senator McCain, for chairing the hearing today. I thank you both not only for your long-term commitment to finding a solution to bringing drug costs down for our consumers and seniors – but also for taking this crucial first step of holding a hearing on Hatch-Waxman reform and the GAAP Act – the bill that Senator McCain and I have introduced to ensure timely access to affordable pharmaceuticals.

"An ad in the Washington Post yesterday paid for by PhRMA reported that 75% of physicians agreed that patent laws are very important to the future of America's medicines. Well, I'm not a doctor, much to the chagrin of my mother, but I couldn't agree more. Continued innovation in pharmaceutical development is key to ensuring that patients have access to life-saving drugs when they need them.

"But the PhRMA ad only tells part of the story. It implies that patent laws were put in place to benefit consumers solely by protecting innovation. There's a flip side. Our patent laws aren't just meant to stimulate innovation. They're also intended to bring scientific knowledge into the public domain – to eventually spur competition and to keep the drug companies from holding a never-ending monopoly over the heads of consumers.

"But in the world of the drug industry right now, the brand companies are extending their monopolies to the detriment of consumers. There are a number of loopholes in the patent laws which drug companies exploit every day to block their low-cost competitors from breaking into the marketplace. Take, for example, Paxil, a drug with $2.1 billion in sales used to treat obsessive-compulsive disorder.

"Glaxo SmithKline sued the first generic applicant, Apotex, in 1998 over a patent intended to expire in 2006. This move automatically delayed competition for 30 months, and has continued to prevent competition while the litigation is ongoing.

"Even if the companies come to resolution on this first patent, Glaxo has listed nine additional patents on the drug in the intervening years since the first lawsuit began – patents on slightly different chemical substances (which have never been approved for marketing by the FDA, but which the company claims are relevant to Paxil), as well as patents on different formulations of the drug. The last of these patents expires in 2018. Most of these new patents will– and already have – invoked additional, multiple 30-month stays against generic competition for Paxil. Each year generic competition is delayed may cost consumers up to $500 million.

"What happened here is that the drug company saw its original patents about to expire and then created new ones to maintain its control over the market. These kinds of practices have become the norm in the drug industry. These companies figure out a new way to keep the dollars rolling in, stooping to new low every day to maintain their exclusivity rights.

"I have recently learned of the latest low to which the big pharmaceutical companies are stooping to block the entry of low-cost, generic drugs. They have begun to seek patents on information related to safety. The FDA has long determined that safety information should be part of the public domain and that it shouldn't prevent generic versions of approved drugs from coming to market.

"In the case of the pain medication, Ultram, five generic versions of it were about to be approved in January of this year. But in February, Ortho McNeill filed a patent on a slightly altered dosing schedule, a schedule which is obvious to most pharmacists, but one which they claim is essential to the safety of the drug.

"Under Hatch-Waxman, patenting this information would at the very least automatically keep the generic off the market for 30 months. If the patent is upheld in the courts, it would prevent competition until 2019. With sales of over $690 million per year, these delays will cost consumers over $3 million per week.

"Prescription drug expenditures are throwing insurers, corporations, and state Medicaid agencies into a tailspin, as they attempt to craft high quality health care benefits that are within the realm of affordability. They're crippling consumers and seniors who can't afford to purchase their drugs or take them every day as prescribed.

"I agree that patent protection is key to saving lives, but I'm sure the doctors surveyed by PhRMA would also agree that a drug can do no good if it is financially out of the reach of patients who depend on it.

"So, with this in mind, I want it to be clear about what this hearing is NOT about. It's not about robbing pharmaceutical companies of legitimate patent protection, it's not about theft of innovation, it's not about taking steps to enact laws that are NOT in the best interest of consumers.

"In fact, it's about just the opposite. It's about examining competition in today's marketplace and revisiting a compromise which was struck nearly 18 years ago.

"In 1984, Congress passed one of the most important and least appreciated pro-consumer laws of the past 2 decades. Hatch-Waxman provided additional patent protection for research-based brand name drugs and created a mechanism to allow less expensive generic equivalents on to the market.

"Hatch-Waxman has saved consumers billions of dollars on pharmaceuticals while helping brand name companies stay profitable and innovative.

"Generic drugs have captured over 44% of the market in terms of number of prescriptions written, and pharmaceutical research and development has increased nearly seven-fold from $4.1 billion in 1985 to $26.4 billion in 2001. The pharmaceutical industry once again topped the Fortune 500 list of most profitable industries.

"But, in recent years, as the profits and stakes have become higher, drug industry lawyers have picked the Hatch-Waxman law clean. Companies are aggressively pursuing extended monopolies through filing weak or invalid patents and engaging in deals which the FTC is increasingly scrutinizing for anti-competitive motives. We must put an end to these abuses.

"Prozac, a blockbuster drug which enjoyed $2.4 billion in revenue in 2001, finally came off patent last August. Since then prices have dropped more than 90%, and estimates indicate that nearly 80% of former Prozac consumers are now using the generic.

"According to these estimates, generic competition for Prozac will save consumers over $1.8 billion this year alone. That is just one drug. With potential savings this significant, Congress has a responsibility to ensure that Hatch-Waxman is working the way it was intended.

"The bill Senator McCain and I have introduced – the Greater Access to Pharmaceuticals (or GAAP) Act seeks to breathe new life into Hatch-Waxman, not by redrawing ideological battle lines, but by restoring the intent of our patent laws. Our intention is not to cut innovators off at the knees and it isn't a freebie for the generic drug industry. It is a pro-consumer bill that restores the balance intended by Hatch-Waxman.

"The bill would eliminate the automatic 30-month stay handed to brand companies who file suit against a generic challenger. It would instead require these companies to allow a court to decide whether their case merits a stay.

"It would prevent abuses like the Paxil and Ultram examples by reducing incentives to list patents that are not truly innovative, but instead are intended solely to extend monopolies.

"The GAAP Act reforms the so-called "180-day rule" by closing the loophole that enables a brand name company to pay a generic manufacturer to stay off the market, effectively putting the kibosh on competition. Closing this loophole would prevent problems like the cases we're discussing here today– the Hytrin case

where Abbott Laboratories allegedly paid Geneva Pharmaceuticals $4.5 million per month to keep their hypertension drug off the market.

"Or the K-Dur 20 case, recently settled by the FTC, in which Schering Plough allegedly paid Upsher-Smith and American Home Products millions of dollars to delay launching a generic potassium chloride supplement.

"Mr. Chairman, as Congress wrestles with the complexity of crafting and paying for a Medicare prescription drug benefit, we must not overlook a straightforward solution to the escalating drug prices facing seniors, businesses, insurers and consumers today.

"If we can ensure fair competition in the pharmaceutical marketplace – a level playing field for both brand and generic companies – then everyone will win.

"I thank you, Mr. Chairman, for holding this important hearing today and look forward to working with you, with Senator McCain, and with the FDA and the FTC to encourage fair marketplace practices – while preserving both safety and intellectual property rights – to provide customers with affordable pharmaceutical alternatives."

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Delegate Address Labels By Conference Id

Michael Kopcha
Dir Strategic Life Cycle Mgmt
Johnson & Johnson
410 George St
New Brunswick, NJ 08901-2021 USA

Kris Larsen
Managing Dir
Interbrand
200 E Randolph
Chicago, IL 60601 USA

James Michael
GlaxoSmithKline
5 Moore Dr, P O Box 13398
Research Triangle Park, NC 27709-3398 USA

Arnaud Partiot
MD
Wyeth Ayerst Research
500 Arcola Rd
Collegeville, PA 19426 USA

Steven Peskin
President
Nelson Managed Solutions
2000 Lenox Dr
Lawrenceville, NJ 08648 USA

Nancy Santilli
Sr Dir
Elan Corp
800 Gateway Blvd
South San Francisco, CA 94080-7085 USA

Anna Stashower
Publisher
Product Management Today
66 Palmer Ave
Bronxville, NY 10708 USA

Kenda Tavakoli
Dir Bus Dev
McKesson HBOC
14805 Bauer Dr
Rockville, MD 20853 USA

Monica Alfaro Welling
Dir Marketing
Allergan
2525 Dupont Dr, P O Box 19534
Irvine, CA 92623 USA

Henry Wixon Esq
Sr Partner
Hale and Dorr LLP
1455 Pennsylvania Ave NW Ste 1000
Washington, DC 20004 USA

Hope Krakoff
Client Mgr
eMaven Inc
345 Summer St
Boston, MA 02210 USA

Gregg Larson PhD
Clinical Dir WW Atheriosclerosis
Pfizer Inc
235 E 42nd St Bldg 235 3rd Fl
New York, NY 10017 USA

Ashish Pal
Dir Global Marketing Allergy Phm
Alcon Labs Inc
6201 S Fwy T6 7
Fort Worth, TX 76134 USA

Cara Pellegrini
Sr Assoc
Elan Corp
800 Gateway Blvd
South San Francisco, CA 94080-7085 USA

Kathleen Riordan
VP Marketing
WRB Communications Inc
4200 Lafayette Ctr Dr Ste J
Chantilly, VA 20151-1208 USA

J Greg Slatter
Scientist
Pharmacia Corp
100 Rte 206 N, P O Box 800
Peapack, NJ 07977 USA

Victor Strecher PhD
President
HealthMedia Inc
130 S 1st St
Ann Arbor, MI 48104 USA

Jean Patrick Tsang PhD MBA
President
Bayser Consulting
4709 Golf Rd #803
Skokie, IL 60076 USA

John Wiedemann
Product Strategist
AstraZeneca
725 Chesterbrook Blvd, P O Box 5677
Wayne, PA 19087-5677 USA

Gregory Zaidel
Dir Bus Dev
Alexion Pharmaceuticals Inc
352 Knotter Dr
Cheshire, CT 06410 USA

Smooth Feed Sheets™ Use template for 5161®

Delegate Address Labels By Conference Id

11/20/2001

Kim Bailey
Marketing Mgr
Celltech Pharmaceutical Inc
P O Box 31766
Rochester, NY 14603 USA

Johanna Bloom
Team Leader Pharmaceuticals
Center for Business Intelligence
500 W Cummings Park, Washington St Ste 5100
Woburn, MA 01801-6503 USA

Bart Classen MD MBA
CEO
Classen Immunotherapies Inc
6517 Montrose Ave
Baltimore, MD 21212 USA

Lance Colwell
Product Mgr
Purdue Pharma LLP
1 Stamford Forum, 201 Tesser Blvd
Stamford, CT 06901-3431 USA

Patrick Crowley
Dir Pharmaceutical Dev
GlaxoSmithKline
1250 S Collegeville Rd, P O Box 5089
Collegeville, PA 19426-0989 USA

Jill Deal Esq
Principal
Fish & Richardson
601 13th St NW
Washington, DC 20005 USA

Marla Fox
Sr Consultant
CanadaDirect
743 Renaud Ave
Montreal, QUE H9P2N1 CANADA

Tony Gross
Dir
GlaxoSmithKline
1600 Vine St 3 Franklin Plz, P O Box 13619
Philadelphia, PA 19102 USA

Seth Houston
Sr Product Marketing Mgr
IMS Health
660 W Germantown Pike
Plymouth Meeting, PA 19462 USA

Mak Jawadeker PhD
Asst Dir Pharm Sciences
Pfizer Inc
Eastern Point Rd Bldg 156
Groton, CT 06340-5146 USA

Janet Benesh
Assoc Dir
Solvay Pharmaceuticals
901 Sawyer Rd
Marietta, GA 30062-2224 USA

Don Bush
VP
Mattson Jack Group
95 Mattson Ave Ste 410
Morristown, NJ 07960 USA

Susan Lavine Coleman
President
NCI Consulting Inc
1 Highland St
Cambridge, MA 02138 USA

Mary Connell
Conference Producer
Center for Business Intelligence
500 W Cummings Park, Washington St
Woburn, MA 01801-6503 USA

Robert DeBartolo
Exec VP
Corbett Healthcare Grp
211 E Chicago Ave
Chicago, IL 60611 USA

Edward Dougherty
Sr VP Patient Registry Services
McKesson HBOC Pharm Prtnrs Grp
7564 Standish Pl Ste 108
Rockville, MD 20855 USA

Gregory Glover MD JD
Partner
Ropes & Gray
1301 K St NW
Washington, DC 20005 USA

Greg Hamilton
Sr Dir Marketing
Express Scripts Inc
3168 Riverport Tech Ctr Dr
Maryland Heights, MO 63043 USA

Alan Jakimo Esq
Partner
Sidley Austin Brown & Wood
875 Third Ave
New York, NY 10022 USA

Joe Khalifa
WRB Communications Inc
4200 Lafayette Ctr Dr Ste J
Chantilly, VA 20151-1208 USA

Pharmaceutical Product Lifecycle Strategies

Bart
Classen MD MBA

Classen Immunotherapies Inc

The Center for Business Intelligence, LLC

Badges must be worn at all times. registration is non-transferrable SP WS:

Pharmaceutical Product Lifecycle Strategies

Nancy
Santilli

Elan Corp

The Center for Business Intelligence, LLC

Badges must be worn at all times. registration is non-transferrable DE WS: B

Pharmaceutical Product Lifecycle Strategies

Tony
Gross

GlaxoSmithKline

The Center for Business Intelligence, LLC

Badges must be worn at all times. registration is non-transferrable DE WS: B

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John
Wiedemann

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- Evaluate switch feasibility
- Assess alternate entry strategies
- Identify collaborative approaches
- Reduce the risk of cannibalization

B: Manage Intellectual Property to Increase Shareholder Value – Financial Models and Analysis to Support Decision-Making

- Develop an invention disclosure program
- Adopt the Rivette/Klein "Grow-Fix-Sell" decision model
- Understand new accounting approaches for intangibles
- Learn about the Black & Scholes option pricing model

Hear Dynamic Presentations and Case Studies on How to:

- Accelerate product launch success through **patient registry programs**
- Successfully introduce a "**discontinuous**" **innovation** to the marketplace
- Benefit by focusing on **brand strategy** vs. brand management
- Optimize sales through **customized patient compliance** programs
- Capitalize on newly-discovered options from **Phase IV clinical studies**
- Form strategic alliances – the critical difference between **co-promotion** and **co-marketing**
- Leverage **novel drug delivery systems** for patent extension
- Understand the impact of impending legislative initiatives on **market exclusivity** strategies
- Gain an appreciation for expectations vs. reality in the **patent extension application process**
- Use **global patent protection** as part of the lifecycle planning process
- Profit by **patenting adverse event information** on your products

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Workshop A: Identify Rx-to-OTC Switch Strategies Early

Pressure to increase profits and deliver shareholder value, coupled with patent expirations, aggressive generic competition and rising costs, necessitate increasing attention to lifecycle management as a vehicle to maximize return on investment. Rx-to-OTC switch is increasingly recognized as more than a strategy of last resort. Proactive switch planning, as part of a total lifecycle plan, can open the door to incremental growth opportunities prior to patent expiration and to identification of switch strategies capable of maximizing total corporate NPV.

Through industry examples and case studies, this workshop makes the case for assessing switch opportunities early in a drug's patent life and offers guidelines for evaluating switch feasibility and success metrics, identifying and assessing alternate entry strategies and identifying collaborative approaches to maximize success.

7:30 *Workshop Registration*

8:30 *Workshop Leader's Welcome and Opening Remarks*

I. The Business Case for Early Switch
- Success stories from industry
- The threat from FDA — The non-switching, antihistamine case study

II. How to Assess Switch Feasibility
- When to begin feasibility assessment
- Key criteria in switch assessment

III. How to Evaluate the Financial Implications of Alternate Entry Strategies
- Identify the products and indications most likely to make money
- Reduce the risk of cannibalization
- Determine optimal switch timing
- Develop a post-switch lifecycle plan
- Develop credible forecasts

IV. Build a Team to Support Corporate ROI Goals
- Criteria for determining a team's make up
- Goal setting and success metrics
- Avoid the common pitfalls of OTC marketing partnerships
- Structure internal incentives to ensure company-wide commitment
- Checkpoints to evaluate success

Workshop B: Manage Intellectual Property to Increase S
Financial Models and Analysis to Support Deci

As industry more carefully examines which drugs merit further investment and which to let go, this workshop offers guidance on where to dedicate time and resources to ensure greater profits. Global patent wars illustrate the value of comprehensive patent planning. The objective of a strategic intellectual property plan is simple: nurture, maximize, maintain and protect the value of the enterprise's intellectual property. Our workshop focuses on a "Modified Eight-Step Lehman Plan," oriented toward patents and named after the former commissioner of the U.S. Patent and Trademark Office and advocate of a substantial portion of this plan. Learn to value intellectual property and business patents to engage in partnerships and business decisions that ensure financial success.

7:30 *Workshop Registration*

8:30 *Workshop Leader's Welcome and Opening Remarks*

I. Conduct an IP Audit
- Identify actions that need to be taken with respect to:
  - existing patents, patent applications and inventions for which applications need to be prepared and prosecuted

II. Create and Maintain Invention Discovery Management Protocols
- Systematically identify and track the enterprise's intellectual property

III. Formulate and Implement a Patent Strategy
- Formulate and implement a patent strategy consisting of a series of patents with claims of varying scope that (borrowing from the Rivette/Klein "IP-3" model) protect core technology, reinforce core patents and control process choke points

IV. Develop an Invention Disclosure Program for Non-Trade Secret Inventions Not Chosen for Patents
- Publicly establish priority of invention as a defensive move with respect to inventions for which neither patent nor trade secret protection will be sought

V. Police and Enforce Intellectual Property
- Identify infringements by third parties
- Periodically review trade press and competitors' marketing materials and regulatory filings for signs of infringement
- Implement procedures for handling reports of alleged infringement and sending standard cease and desist notices to infringers; and litigate when necessary

VI. Defend Against Claims of Infringement
- Defend the enterprise against claims of infringement by third parties

VII. Portfolio Maintenance and Growth
- Adopt the Rivette/Klein "Grow-Fix-Sell (License)" patent cycle model

VIII. Valuation of Patents
- Understand different methods of valuing patents for purposes of making grow-fix-sell (license) decisions using econometric valuation methods that focus on aggregate statistics
- Legislative approaches that endeavor to balance political issues courts that use Georgia-Pacific factors to set license fees

a Drug's Patent Life

12:00 *Close of Workshop*

There will be a 30-minute networking and refreshment break at 10:00 am

— About Your Workshop Leader —

Susan Lavine Coleman, President, NCI Consulting joined Nelson Communications in 1990 as Vice President of NCI Consulting and was named President in 1995. Since its creation in 1989, NCI Consulting has become a leader in providing long-term strategic planning, business development and marketing plan optimization support to the healthcare industry. Clients include many of the largest U.S. pharmaceutical manufacturers, including **Pfizer, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Novartis and Pharmacia.** This has led to work in a broad range of therapeutic categories, including respiratory diseases, cardiovascular, metabolics, analgesics, anesthesiology, anti-virals, urology, women's health, dermatology and many others. In addition, NCI Consulting has a major sub-practice in OTC switch assessment and implementation, having evaluated over 200 switch candidates, and having worked on twenty-nine actual switches, in just the last eight years. Prior to joining Nelson Communications, Susan was U.S. Director for Therapeutic Skin Care at Johnson & Johnson, as well as Worldwide Coordinator for adult dermatology strategy. Earlier, she led major brand franchises in analgesics and in oral health products. Susan has a masters degree in Marketing and Finance from the Kellogg School of Management at Northwestern University.

areholder Value — on-Making

- Venture finance models that focus on discounted cash flow models
- New accounting approaches for "intangibles"
- Financial modeling tools like the Black & Scholes option pricing model
- The public equities market- the final arbiter

:00 *Close of Workshop*

re will be a 30-minute networking and refreshment break at 10:00 am

— About Your Workshop Leader —

n L. Jakimo, Esq., Partner, Sidley Austin Brown & Wood joined the firm in 0 and was appointed a partner in 1989. He has worked in the venture and nology field for over 20 years, with particular emphasis in the life science and rmation science industries. In the life science industry, Mr. Jakimo's experience udes work with companies engaged in various aspects of developing and mercializing pharmaceuticals, biotechnology and genomics/proteomics nology. In the information science industry, Mr. Jakimo's experience includes panies engaged in various aspects of developing and commercializing computer lware and software, communications equipment, networking and internetworking ices and electronics. Mr. Jakimo's assignments encompass private placements and lic offerings of equity and debt securities, as underwriters' counsel, investors' nsel and issuer's counsel, technology licensing and development, strategic aborations, mergers and acquisitions, and other contractual arrangements by panies located in the Americas, Asia and Europe. Securities offerings in which Jakimo has participated include seed stage, venture and mezzanine round equity ate placements by start-up and emerging companies, initial public offerings and w-on private and public offerings by public companies. Intellectual property ters play a key role in many of Mr. Jakimo's assignments, particularly with respect ue diligence, drafting of agreements and licenses and preparation of disclosure uments, such as private placement memoranda and prospectuses. Jakimo received a BA in Mathematics from Colgate University and an MBA and from Harvard University.

"Drugs with combined 1999 s

MAIN CONFERENCE

Day One — Thursday, November 15, 2001

12:00 *Main Conference Registration*

1:15 *Chairman's Welcome and Opening Remarks*

Gregory A. Zaidel, Director of Business Development
Alexion Pharmaceuticals, Inc.

Gregory A. Zaidel has 17 years of pharmaceutical industry experience in [illegible] sales, marketing, strategic planning, business development and management consulting. He is responsible for commercial development of the Corporation's overall business operations. Prior to joining Alexion, Greg [illegible] Rorer Corporation's Pharmaceutical Division where he was the North American [illegible] representative for the development of new products and strategic alliances in several of the division's therapeutic areas. [illegible]

1:30 **The Payoff of Customer-Focused Marketing**

Pharmaceutical Perspective

- Maximize the fit between the firm's capabilities and customer needs
- Define and profile the "customer"
  - >payors
  - >physicians
  - >patients
- Case example

Ashish D. Pal, Director, Global Marketing – Allergy, Pharmaceutical
Alcon Laboratories, Inc.

2:15 **Prepare the Marketplace for Your Product — Engineer an Environment for Success**

Strategic market planning uncovers the greatest points of leverage and addresses inhospitable climates. To assess the marketplace and engineer a climate where your product is poised for success this session covers the following:

Medical Device Perspective

- How to introduce a "discontinuous" innovation
  - >what does your target know?
  - >what does your target need to know?
  - >articulate where your product fits within the category
- Understand what it takes to be successful
  - >pre-launch planning
  - >strategic reimbursement
  - >commercial sales
- Ongoing market surveillance
  - >uncover insights
  - >make insights actionable

Claudia Graham, PhD, MPH, Vice President, Marketing and Product Development, **MiniMed, Inc.**

3:00 *Networking and Refreshment Break*

les of $100 billion will lose patent protection by 2005." —Datamonitor

3:15 **Accelerate Product Launch Success through Patient Registry Programs**

- Engage the interest of important audiences in the post-approval, pre-launch phase
  - >physicians, hospitals
- Integrate analysis to improve
  - >payer, physician and patient acceptance
- Utilize enrollment and program summaries as a point-of-entry strategy with
  - >gatekeepers, opinion leaders
- Ethical, privacy and regulatory considerations

Edward J. Dougherty, Senior Vice President, **McKesson HBOC Pharmaceutical Partners Group**

4:00 **Use Strategic Brand Management to Build Equity for Increased Profitability**

Creating and managing brands can add layers of value to hard-won and fiercely defended intellectual property. Strategic investment in branding holds promise for building connections and affinity by prescribers and patients for branded products to help stave off generic competition and price sensitivity.

- Why the sudden discussion about brands?
- Benefits of focusing on brand strategy vs. brand management tactics
- Value derived

Bob DeBonnis, Executive Vice President, **Corbett Healthcare Group**

5:00 *Close of Day One*

5:00 - 6:00 ***Wine & Cheese Networking Reception***

Join colleagues and friends in a relaxed setting.

Day Two — Friday, November 16, 2001

7:30 *Continental Breakfast*

8:00 *Chairman's Review of Day One*

Gregory A. Zaidel, Director of Business Development, **Alexion Pharmaceuticals, Inc.**

8:15 **Optimize Sales through Customized Patient Compliance Programs**

- Application for short- and long-term therapies
  - >lifestyle drugs
  - >disease management
- Appeal to payors, prescribers and patients
- Move the needle for success in terms of patient outcomes and sales
- Implications for insulation against generic and innovator competitors
- Fine-tuning for new drug delivery systems
- Industry case study

Hejar J. Sarcher, PhD, Director, **University of Michigan Health Media Research Laboratory**

9:00 **Medical/Marketing Strategies for Phase IV Clinical Trials — New Emphasis, Greater Priority**

- Begin with an end in mind — The importance of study design
- Physician and patient targeting
- Identify opportunities through epidemiology
- Evaluate the costs and benefits of alternatives
- Create programs to capitalize on newly-discovered options

Greg H. Larsen, PhD, Clinical Director, Worldwide Antiinfectives, **Pfizer**

9:45 *Networking and Refreshment Break*

10:15 **Form Strategic Alliances to Support the Lifecycle Plan**

- Criteria for identifying and selecting partners
- Critical differences between co-promotion and co-marketing
- What represents the best option for your product?
- Division of roles and responsibilities?
- Incentive structures
- Success metrics
- Case studies

Gregory A. Zaidel, Director of Business Development, **Alexion Pharmaceuticals, Inc.**

11:00 **Improve Product Positioning and Product Enhancement through Novel Delivery Systems and Effective Lifecycle Management**

Drug delivery technology and systems add value beyond simply delivering a drug. They can help improve a pharmaceutical company's product pipeline as well as improve marketing potential, commercialization and even breathe new existence into a product's lifecycle. How do you leverage a drug delivery system to improve marketability and new product positioning?

- Identify when to use a drug delivery product to help position your product
  - >drugs that can benefit
  - >technologies that work well with product enhancement
  - >strategies to incorporate drug delivery into your marketing
  - >does market research really give accurate direction for the use of novel formulations?
- Understand how these deals are structured
- Utilize drug delivery to gain competitive advantage

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- Leverage drug delivery systems for patent extension
  - >understand when to use this strategy
  - >identify the right delivery system
  - >best technologies
  - >how generic companies are fighting back

Mal Jawadekar, PhD, Assistant Director, Pharmaceutical Sciences, Pfizer

11:45 *Luncheon*

1:15 **Understand the Impact of Impending Legislative Initiatives on Market Exclusivity Strategies**

- Review of current market exclusivity provisions, including
  - >data protection
  - >the generic drug approval process
  - >505(b)(2) drugs
  - >patent term extensions
  - >pediatric exclusivity
  - >orphan drugs
- Analysis of the stated motivations for, and potential impacts of
  - >proposed Hatch-Waxman reforms
  - >pending legislative changes in the Shumer-McCain and Leahy bills
- An update on
  - >the likely near-term changes
  - >the implications for market exclusivity strategies

Gregory J. Glover, MD, JD, Partner, Ropes & Gray

2:00 **Maximize Global Patent Protection as Part of the Lifecycle Planning Process**

- The benefits of managing a patent globally
- Resolve the tension between maximizing product lifecycle revenue on a global basis while ensuring reasonable prices
- The importance of "safe harbor" provision in the U.S. (35 U.S. Sec. 271(e)(1) of the Hatch-Waxman Act)
- Understand the impact of the European Union's (EU) challenge of the Canadian Patent Act's "safe harbor" provisions as a "stalking horse" for attack on U.S. "safe harbor" provisions
- "Safe harbor" held legal under TRIPS by World Trade Organization (WTO) dispute panel
- Pressure for worldwide "safe harbor" provisions resulting from the WTO dispute panel decision.
  - >need for a statutory "Bolar" exemption in the EU
- Update on the status of generic manufacturers' ability to work on drugs prior to patent expiration in major European markets

Jill B. Dell, Esq., Principal, Fish & Richardson

2:45 *Networking and Refreshment Break*

3:00 **The Patent Extension Application Process — Expectations vs. Reality**

- Overview of recent rulings
- What's working, what's not?
- Factors that impact the probability of getting approval
- Financial costs
- Timelines

Mark Farber, Esq., Chief Patent Counsel to Alexion Pharmaceuticals, Inc.

3:45 **Patent Adverse Event Profiles — A Competitive Necessity**

Companies have patented new expanded uses and novel dosing schedules of drugs in the past. Recently the U.S. Patent and Trade Office has indicated that new safer uses of a drug, are patentable (US 6,219,674) where the safer use involves disclosing of new adverse event information. Your company may maintain proprietary control of its drugs after their composition patents have expired by the discovery and patenting of new adverse event information. Learn how to profit from the discovery of new adverse event information on your products. Learn why patenting the adverse event profiles of drugs is essential to compete in today's market.

- Increase profits while making your products safer
- Develop a low cost patent portfolio of adverse events
- Learn about the risks of allowing your competitors to find new adverse events of your drugs
- Prevent "me too" drugs by discovering class-related adverse events

John B. Clogan, MD, MBA, CEO, Classen Immunotherapies, Inc.

4:30 *Close of Conference*

Who Should Attend?

Vice Presidents and Directors of:
Marketing
Business Development
Alliances
Product Development
Licensing
Corporate Development
Strategic Planning

Maximize Your Networking Opportunities

Join Classen Immunotherapies, Inc. in showcasing your products and services to senior-level decision makers. CBI's Pharmaceutical Product Lifecycle Strategies conference offers you an excellent opportunity to maximize your 2001 marketing dollars through these showcase opportunities:

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- Alcon Laboratories explains its customer-focused approach
- McKesson HBOC Pharmaceutical Partners Group discusses patient registry programs
- MiniMed describes how to introduce a "discontinuous" innovation to the market
- Pfizer outlines medical/marketing strategies for Phase IV clinical trials
- Ropes & Gray discusses market exclusivity strategies

Conference Documentation Binders

If you are unable to attend CBI's Pharmaceutical Product Lifecycle Strategies conference, or you would like extra copies for your colleagues, you can order your documentation binder today. Don't miss out on the valuable information presented by industry leaders exclusively at this event. The conference documentation binder is available for only $295, add $50 for international shipments. The binder includes speaker handouts, articles and presentations. Simply fill out the order form and the binder will be shipped to you 2 weeks after the conference occurs.

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Hi John,

Here is the confirmation for the teleconference with Steve Cartt.

Subject: AE Patent Strategies
When: Friday, January 11th
Time: 5pm - 6pm EST; 2pm-3pm PST
Participants: Steve Cartt, Nancy Santilli, Jean Duvall, Mark Hoch (unconfirmed)

Call in information: 1-800-525-2464
Passcode: 537996
Call Owner: Steve Cartt

Let me know if you need any more information. I can be reached at 858-457-7461.
Have a great meeting,

Paula Chapman
Elan Pharmaceuticals
Administrative Assistant, Strategic Marketing
Telephone: 858-457-7461
Fax: 858-558-3713
E-mail: paula.chapman@elan.com

****
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Thank you for your co-operation.
****

Bart -- great suggestions. I appreciate your help on these matters, and I feel confident we will make this work. Will keep you posted.....Steve

-----Original Message-----
From: Bart Classen [mailto:classen@vaccines.net]
Sent: Tuesday, May 21, 2002 4:57 AM
To: Cartt, Steve
Subject: patents

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer
U.S.A.
Classen Immunotherapies, Inc.
Tel : 410.377.4549
Classen@vaccines.net
Fax : 410.377.8526

6517 Montrose Avenue
Baltimore, MD 21212

e-mail:

May 22, 2002

Mr. Steve Cartt
Elan Pharmaceuticals
800 Gateway Boulevard
South San Francisco
San Francisco, CA 94080

Dear Steve,

I spoke to Ms. Duvall yesterday and made the following suggestions for you
consideration.

* You may be able to discover additional information on the existing adverse event, or any other adverse event as described below, to allow you to obtain a patent. For example the adverse event may be more common or limited to people with predisposing conditions such as race, age, sex, prior medical conditions, or taking OTC medicines. Also the adverse event may be specific to one Cox-2 inhibitor or to all Cox-2 inhibitors. Either way you can obtain a patent.

If the adverse event is only present with one but not all Cox-2 you

can
claim: a method of administering your drug with one or more Cox-2 inhibitors excluding VIOX.

If the adverse event is found with all Cox-2 inhibitors you can claim: A
methods administering your drug with one or more NSAIDs excluding the class of Cox-2 inhibitors

If the adverse event is found with all compounds with a similar side chain, Y, you can claim: A method of reducing adverse event X associated with you drug by avoiding the coadministration of drugs containing side chain Y.

If the adverse event involves dizzyness or drawsyness one could determine
if a warning about opertaing a car, plane, machinery is appropriate or if there is an additive effect with OTCs like Benadryl that also cause drawsiness.

* If you can not find new patentable information described above you may be able to license the invention, discovery of the adverse event, from the person who first described the adverse event or who first described an association (series of adverse events). There may be several different inventions so there may be several different inventors. One may be willing to license the invention.

* You may want to use additional databases to search for adverse events even if the current adverse event is patentable. Discovery of additional patentable adverse event information will strengthen your patent position. You could use your information pertaining to reports of possible adverse events to formulate ideas for epidemiology studies. You could generate patentable adverse event information by simply following up on some of the suggested adverse events listed in your product insert. For example you can search an outside database for safety information on "chronic use" and to generate human data to expand on the animal toxicity, in particular cardiovascular and ophthalmic complications. Information can be obtained on side effects when used during labor, pregnancy, pediatrics, and in the elderly. The epidemiology studies can be performed in one or more of the many existing databases. Several examples include Kaiser Permanente and LDS

Hospital in Salt Lake City. Kaiser's database has information on outpatients and inpatients while LDS is limited solely to inpatients.

* If you desire additional help in locating patentable adverse event information I am available for hire as a consultant.

I will send you information on databases today.

Sincerely,

Bart

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XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Bart -- in terms of "prior art" concersn taht we had had, we actually seem to be ok on the drug interaction opportunity we had discussed. Right now we are working to collect some additional information to strengthen our position related to this strategy. Will keep you posted. REgards, Steve

-----Original Message-----
From: Bart Classen [mailto:classen@vaccines.net]
Sent: Thursday, June 13, 2002 5:26 AM
To: Cartt, Steve
Subject: Adverse events

I am writing to enquire how things are going. Have you found a data source willing to help you or are you still in serach of one? I tried to call you but you have not been in. If you need more ideas we should talk some more.

Bart Classen

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PRESS RELEASE

Contacts:
James E. Green, Executive Vice President, Corporate Affairs
423-989-8125
David E. Robinson, Senior Director, Corporate Affairs
423-989-7045

King Pharmaceuticals

FOR IMMEDIATE RELEASE

KING PHARMACEUTICALS REPORTS THIRD-QUARTER 2006 FINANCIAL RESULTS

BRISTOL, TENNESSEE, November 9, 2006 - King Pharmaceuticals, Inc. (NYSE:KG) announced today that total revenues were $492 million during the third quarter ended September 30, 2006, compared to $518 million in the third quarter of 2005. Including special items, net earnings equaled $90 million and diluted earnings per share equaled $0.37 during the third quarter ended September 30, 2006, compared to net income of $122 million and diluted earnings per share of $0.50 in the same period of the prior year. Excluding special items, net earnings equaled $106 million and diluted earnings per share equaled $0.44 during the third quarter ended September 30, 2006, compared to net earnings of $125 million and diluted earnings per share of $0.52 in the third quarter of 2005.

For the nine-month period ended September 30, 2006, total revenues were $1.48 billion compared to $1.35 billion for the nine-month period ended September 30, 2005. Including special items, net income equaled $252 million and diluted earnings per share equaled $1.04 during the nine-month period ended September 30, 2006, compared to net income of $212 million and diluted earnings per share of $0.88 during the same period of the prior year. Excluding special items, net earnings equaled $324 million and diluted earnings per share equaled $1.33 for the nine-month period ended September 30, 2006, compared to net earnings of $308 million and diluted earnings per share of $1.27 in the same period of 2005.

Brian A. Markison, President and Chief Executive Officer of King, stated, "We are pleased with our continued solid financial performance and our accomplishments during the third quarter. Importantly, we strengthened our portfolio with the launch of Glumetza™, a new generation metformin product for patients with Type II diabetes, and our agreement to acquire the rights to Avinza®, a true once-a-day morphine product."

Mr. Markison emphasized, "Glumetza™ is an excellent complement to our cardiovascular/metabolics franchise and Avinza® significantly strengthens our growing pain portfolio, positioning us to become a leader in pain management. We expect to close the Avinza® acquisition on or about December 31, 2006. In the interim, our sales force is promoting the product pursuant to a separate copromotion agreement which terminates in January 2007."

Mr. Markison added, "We are continuing to focus on business development opportunities in our key therapeutic areas to further improve our development pipeline, which includes four products in Phase III and two products in Phase II. Additionally, we expect T-62, our investigational drug for the treatment of neuropathic pain, to enter Phase II in the first half of 2007. As our pipeline continues to build momentum, we expect to report results from several key clinical programs next year."

Net revenue from branded pharmaceuticals totaled $433 million for the third quarter of 2006, a 5% decrease from $455 million during the third quarter of 2005. This difference was primarily due to previously disclosed changes in reserve estimates and increases in wholesale inventory levels of the Company's products in the third quarter of 2005 that each positively benefited net revenues during that quarter.

Altace® (ramipril) net sales totaled $159 million during the third quarter of 2006 compared to $174 million during the third quarter of 2005.

Net sales of Skelaxin® (metaxalone) totaled $106 million during the third quarter of 2006 compared to $116 million during the same period of the prior year.

Thrombin-JMI® (thrombin, topical, bovine, USP) net sales totaled $70 million during the third quarter of 2006 compared to $54 million during the third quarter of 2005. Net sales of this product during the third quarter of 2006 benefited from an increase in wholesale inventory levels which remain within a normalized range.

Net sales of Sonata® (zaleplon) totaled $19 million during the third quarter of 2006 compared to $20 million during the third quarter of the prior year.

Levoxyl® (levothyroxine sodium tablets, USP) net sales totaled $25 million during the third quarter ended September 30, 2006 compared to $36 million during the third quarter of 2005.

King's Meridian Medical Technologies business contributed revenue totaling $37 million during the third quarter of 2006 compared to $38 million during the same period of the prior year.

Royalty revenues, derived primarily from Adenoscan® (adenosine), totaled $19 million during the third quarter ended September 30, 2006, compared to $22 million during the third quarter of 2005. During the third quarter ended September 30, 2006, net revenue from contract manufacturing equaled $3 million.

As of September 30, 2006, the Company's cash and cash equivalents and investments in debt securities totaled approximately $918 million. During the third quarter of 2006, the Company generated cash flow from operations of approximately $127 million. King expects to use cash to consummate its planned acquisition of Avinza®. Additionally, King plans to utilize its cash position to fuel its business development initiatives and aggressively invest in the further development of products in its pipeline. Accordingly, the Company continues to believe that its total investment in research and development for the full year of 2006 could exceed $150 million.

Webcast Information

King will conduct a webcast today to discuss the Company's third quarter 2006 financial results and other matters pertaining to its business. Interested persons may listen to the webcast on

Thursday, November 9, 2006, at 11:00 a.m., E.S.T. by clicking the following link to register and then joining the live event with the same URL:

http://www.kingpharm.com/web_casts.asp

If you are unable to participate during the live event, the webcast will be archived on King's web site at the same link for not less than 14 days after the webcast.

About Glumetza™
Glumetza™ is a once-daily, extended-release formulation of metformin HCl indicated as an adjunct to diet and exercise to improve glycemic control in adult patients (18 years and older) with Type II diabetes. Glumetza™ may be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adults.

Glumetza™ is contraindicated in patients with renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels greater than or equal to 1.5 mg/dL in males and greater than or equal to 1.4 mg/dL in females), congestive heart failure, known hypersensitivity to metformin HCl, and acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma. As with all metformins, there is a warning regarding lactic acidosis with Glumetza™. For additional information on the product, please access the package insert at http://www.depomedinc.com/glumetza_Prescribing_Info.pdf.

About Avinza®
Avinza® is an extended-release opioid agent for patients requiring continuous, around-the-clock analgesia for an extended period of time. It is ideally suited for low-risk populations for the treatment of cancer and severe, chronic non-malignant pain conditions. It contains morphine in an extended release form, allowing for once-daily dosing. Avinza® is covered by a formulation patent that extends through November 2017.

Because Avinza® is an extended-release product, it should not be chewed, crushed, or dissolved due to the risk of rapid release and absorption of a potentially fatal dose of morphine. Avinza® should not be taken with alcohol or drug products containing alcohol. The most common serious adverse events reported with administration of Avinza® are vomiting, nausea, death, dehydration, dyspnea, and sepsis. Avinza® is contraindicated in patients with known hypersensitivity to morphine, morphine salts, or any components of the product.

About Special Items
Under Generally Accepted Accounting Principles ("GAAP"), "net earnings" and "diluted earnings per share" include special items. In addition to the results determined in accordance with GAAP, King provides its net earnings and diluted earnings per share results for the quarters and nine months ended September 30, 2006 and 2005, excluding special items. These non-GAAP financial measures exclude special items which are those particular material income or expense items that King considers to be unrelated to the Company's ongoing, underlying

business, non-recurring, or not generally predictable. Such items include, but are not limited to, merger and restructuring expenses; non-capitalized expenses associated with acquisitions, such as in-process research and development charges and one-time inventory valuation adjustment charges; charges resulting from the early extinguishment of debt; asset impairment charges; expenses of drug recalls; and gains and losses resulting from the divestiture of assets. King believes the identification of special items enhances the analysis of the Company's ongoing, underlying business and the analysis of the Company's financial results when comparing those results to that of a previous or subsequent like period. However, it should be noted that the determination of whether to classify an item as a special item involves judgments by King's management. A reconciliation of non-GAAP financial measures referenced herein and King's financial results determined in accordance with GAAP is provided below.

About King Pharmaceuticals

King, headquartered in Bristol, Tennessee, is a vertically integrated branded pharmaceutical company. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry through the development, including through in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products in attractive markets and the strategic acquisition of branded products that can benefit from focused promotion and marketing and product life-cycle management.

Forward-looking Statements

This release contains forward-looking statements which reflect management's current views of future events and operations, including, but not limited to, statements pertaining to the planned closing of the Avinza® acquisition; statements pertaining to the expected reporting of clinical trial results; statements pertaining to the Company's business development initiatives and product pipeline; statements pertaining to the Company's expected investment in research and development for 2006; statements pertaining to the Company's planned use of cash; and statements pertaining to the Company's planned webcast to discuss its third-quarter 2006 results. These forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from the forward-looking statements. Some important factors which may cause actual results to differ materially from the forward-looking statements include dependence on King's ability to continue to acquire branded products, including products in development; dependence on King's ability to continue to successfully execute the Company's strategy and to continue to capitalize on strategic opportunities in the future for sustained long-term growth; dependence on King's ability to successfully integrate its acquisitions; dependence on King's ability to complete its acquisition of Avinza® as planned; dependence on the high cost and uncertainty of research, clinical trials, and other development activities involving pharmaceutical products in which King has an interest; dependence on the unpredictability of the duration and results of the U. S. Food and Drug Administration's ("FDA") review of Investigational New Drug applications ("IND"), New Drug Applications ("NDA"), and Abbreviated New Drug Applications ("ANDA") and/or the review of other regulatory agencies worldwide that relate to those projects; dependence on the availability and cost of raw materials; dependence on no material interruptions in supply by contract manufacturers of King's products;

dependence on the potential effect on sales of the Company's existing branded pharmaceutical products as a result of the potential development and approval of a generic substitute for any such product or other new competitive products; dependence on the potential effect of future acquisitions and other transactions pursuant to the Company's growth strategy; dependence on whether King incurs research and development expenses as planned; dependence on King's compliance with FDA and other government regulations that relate to the Company's business; dependence on King's ability to conduct its webcast as currently planned on November 9, 2006; dependence on changes in general economic and business conditions; changes in current pricing levels; changes in federal and state laws and regulations; changes in competition; unexpected changes in technologies and technological advances; and manufacturing capacity constraints. Other important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the "Risk Factors" section and other sections of King's Form 10-K for the year ended December 31, 2005 and Form 10-Q for the quarter ended June 30, 2006, which are on file with the U.S. Securities and Exchange Commission ("SEC"). King does not undertake to publicly update or revise any of its forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

KING PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	September 30, 2006 (Unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 138,054	$ 30,014
Investments in debt securities	779,545	494,663
Restricted cash	-	130,400
Accounts receivable, net	255,746	223,581
Inventories	186,770	228,063
Deferred income tax assets	69,153	81,777
Prepaid expenses and other current assets	102,356	59,291
Total current assets	1,531,624	1,247,789
Property, plant and equipment, net	303,822	302,474
Intangible assets, net	924,828	967,194
Goodwill	121,152	121,152
Deferred income tax assets	258,498	231,032
Marketable securities	13,508	18,502
Other assets	94,112	77,099
Total assets	$ 3,247,544	$ 2,965,242
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 80,810	$ 84,539
Accrued expenses	471,695	519,620
Income taxes payable	20,617	22,301
Current portion of long-term debt	4,257	345,000
Total current liabilities	577,379	971,460
Long-term debt	400,000	-
Other liabilities	23,894	20,360
Total liabilities	1,001,273	991,820
Commitments and contingencies		
Shareholders' equity:		
Common shares no par value, 300,000,000 shares authorized, 243,113,666 and 242,493,416 shares issued and outstanding, respectively	1,238,535	1,213,482
Retained earnings	1,006,938	754,953
Accumulated other comprehensive income	798	4,987
Total shareholders' equity	2,246,271	1,973,422
Total liabilities and shareholders' equity	$ 3,247,544	$ 2,965,242

KING PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
REVENUES:				
Total revenues	$ 491,706	$ 518,032	$ 1,475,586	$ 1,349,596
OPERATING COSTS AND EXPENSES:				
Cost of revenues , exclusive of depreciation, amortization and impairments shown below	106,473	92,257	305,925	257,259
Excess purchase commitment	-	-	-	(1,582)
Total cost of revenues	106,473	92,257	305,925	255,677
Selling, general and administrative, exclusive of co-promotion fees and Mylan transaction costs	112,802	107,232	320,517	292,643
Special legal and professional fees	(5,502)	4,406	(1,037)	13,268
Mylan transaction costs	-	466	-	3,898
Co-promotion fees	50,294	70,346	162,615	162,588
Total selling, general, and administrative expense	157,594	182,450	482,095	472,397
Depreciation and amortization	36,361	31,352	109,273	112,698
Accelerated depreciation	1,472	-	1,472	-
Total depreciation and amortization	37,833	31,352	110,745	112,698
Research and development	38,419	24,049	102,931	53,021
Research and development-in-process upon acquisition	25,000	-	110,000	-
Total research and development	63,419	24,049	212,931	53,021
Intangible asset impairment	-	-	279	126,923
Restructuring charges	3,202	597	3,194	2,603
Gain on sale of products	-	(20)	-	(1,458)
Total operating costs and expenses	368,521	330,685	1,115,169	1,021,861
OPERATING INCOME	123,185	187,347	360,417	327,735
OTHER INCOME (EXPENSE):				
Interest expense	(1,894)	(3,136)	(7,925)	(8,876)
Interest income	8,489	5,253	22,842	11,463
Gain (loss) on investment	-	1,040	-	(6,182)
(Loss) gain on early extinguishment of debt	(11)	-	698	-
Other, net	101	(751)	(613)	(2,047)
Total other income (expense)	6,685	2,406	15,002	(5,642)
INCOME FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	129,870	189,753	375,419	322,093
Income tax expense	40,020	67,109	123,931	111,302
INCOME FROM CONTINUING OPERATIONS	89,850	122,644	251,488	210,791
DISCONTINUED OPERATIONS:				
Income (loss) from discontinued operations	865	(1,226)	775	2,607
Income tax expense (benefit)	310	(439)	278	989
Total income (loss) from discontinued operations	555	(787)	497	1,618
NET INCOME	$ 90,405	$ 121,857	$ 251,985	$ 212,409
Basic net income per common share	$ 0.37	$ 0.50	$ 1.04	$ 0.88
Diluted net income per common share	$ 0.37	$ 0.50	$ 1.04	$ 0.88
Shares used in basic net income per share	242,256	241,755	242,163	241,737
Shares used in diluted net income per share	242,798	241,907	242,711	241,831

KING PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
EXCLUDING SPECIAL ITEMS - NON GAAP
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
REVENUES:				
Total revenues	$ 491,706	$ 518,032	$ 1,475,586	$ 1,349,596
OPERATING COSTS AND EXPENSES:				
Cost of revenues , exclusive of depreciation and amortization shown below	106,473	92,257	305,925	257,259
Selling, general and administrative, exclusive of co-promotion fees and Mylan transaction costs	112,802	107,232	320,517	292,643
Co-promotion fees	50,294	70,346	162,615	162,588
Total selling, general, and administrative expense	163,096	177,578	483,132	455,231
Depreciation and amortization	36,361	31,352	109,273	112,698
Research and development	38,419	24,049	102,931	53,021
Total operating costs and expenses	344,349	325,236	1,001,261	878,209
OPERATING INCOME	147,357	192,796	474,325	471,387
OTHER INCOME (EXPENSE):				
Interest expense	(1,894)	(3,136)	(7,925)	(8,876)
Interest income	8,489	5,253	22,842	11,463
Other, net	101	(751)	(613)	(2,047)
Total other income	6,696	1,366	14,304	540
INCOME BEFORE INCOME TAXES	154,053	194,162	488,629	471,927
Income tax expense	48,430	68,797	164,690	163,767
NET INCOME	$ 105,623	$ 125,365	$ 323,939	$ 308,160
Basic net income per common share	$ 0.44	$ 0.52	$ 1.34	$ 1.27
Diluted net income per common share	$ 0.44	$ 0.52	$ 1.33	$ 1.27
Shares used in basic net income per share	242,256	241,755	242,163	241,737
Shares used in diluted net income per share	242,798	241,907	242,711	241,831

KING PHARMACEUTICALS, INC.
RECONCILIATION OF NON-GAAP MEASURES
(in thousands, except per share data)
(Unaudited)

The following tables reconcile Non-GAAP measures to amounts reported under GAAP:

	Three Months Ended September 30, 2006	EPS	Nine Months Ending September 30, 2006	EPS
Net income, excluding special items	$ 105,623		$ 323,939	
Diluted income per common share, excluding special items		$ 0.44		$ 1.33
SPECIAL ITEMS:				
Special legal and professional fees (selling, general, and administrative)	5,502	0.02	1,037	0.01
Accelerated depreciation (other operating costs and expenses)	(1,472)	(0.01)	(1,472)	(0.01)
Research and development -in-process upon acquisition (other operating costs and expenses)	(25,000)	(0.10)	(110,000)	(0.45)
Intangible asset impairment (other operating costs and expenses)	-	-	(279)	(0.00)
Restructuring charges (other operating costs and expenses)	(3,202)	(0.01)	(3,194)	(0.01)
(Loss) gain on early extinguishment of debt (other income (expense))	(11)	(0.00)	698	0.00
Income from discontinued operations	865	0.00	775	0.00
Income tax benefit from special items	8,100	0.03	40,481	0.17
Net income	$ 90,405		$ 251,985	
Diluted income per common share, as reported under GAAP		$ 0.37		$ 1.04

	Three Months Ended September 30, 2005	EPS	Nine Months Ending Septmeber 30, 2005	EPS
Net income, excluding special items	$ 125,365		$ 308,160	
Diluted income per common share, excluding special items		$ 0.52		$ 1.27
SPECIAL ITEMS:				
Excess purchase commitment (cost of goods sold)	-	-	1,582	0.01
Special legal and professional fees (selling, general, and administrative)	(4,406)	(0.02)	(13,268)	(0.05)
Mylan transaction costs (selling, general, and administrative)	(466)	(0.00)	(3,898)	(0.02)
Intangible asset impairment (other operating costs and expenses)	-	-	(126,923)	(0.52)
Restructuring charges (other operating costs and expenses)	(597)	(0.00)	(2,603)	(0.01)
Gain on sale of products (other operating costs and expenses)	20	0.00	1,458	0.01
Gain (loss) on investment (other income (expense))	1,040	0.00	(6,182)	(0.03)
(Loss) income from discontinued operations	(1,226)	(0.01)	2,607	0.01
Income tax benefit from special items	2,127	0.01	51,476	0.21
Net income	$ 121,857		$ 212,409	
Diluted income per common share, as reported under GAAP		$ 0.50		$ 0.88

KING PHARMACEUTICALS, INC.

SUMMARY RECONCILIATION OF SPECIAL ITEMS FOR THE QUARTERS ENDED SEPTEMBER 30, 2006 AND 2005

King recorded special items during the third quarter ended September 30, 2006, resulting in a net charge of $23 million, or $15 million net of tax, primarily due to a $25 million charge related to acquired in-process research and development associated with King's collaboration with Arrow and certain of its affiliates to commercialize novel formulations of Altace®.

During the three months ended September 30, 2005, King recorded special items resulting in a net charge of $6 million, or $4 million net of tax, primarily due to professional fees associated with government inquiries and private plaintiff securities litigation.

KING PHARMACEUTICALS, INC.
SUMMARY RECONCILIATION OF SPECIAL ITEMS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005

King recorded special items during the nine months ended September 30, 2006, resulting in a net charge of $112 million, or $72 million net of tax, primarily due to $110 million in charges related to acquired in-process research and development associated with King's entry into a strategic collaboration with Arrow and certain of its affiliates to commercialize novel formulations of Altace®.

During the nine months ended September 30, 2005, King recorded special items resulting in a net charge of $147 million, or $96 million net of tax, primarily due to an intangible asset impairment charge related to Sonata®.

EXECUTIVE OFFICES

KING PHARMACEUTICALS, INC.
501 FIFTH STREET, BRISTOL, TENNESSEE 37620

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